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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,177	11/15/2000	Glen H. Erikson	E1047/20048	3217

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/713,177	ERIKSON ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on January 29, 2004 has been entered.

2. Claims 1-63 are pending.

3. This application is filed on November 15, 2000 and claims priority to US Patent application Nos. 09/664,827, filed on September 19. 2000, 09/613,263, filed on July 10, 2000, and 09/468,679, filed on December 21, 1999.

Response to Arguments

4. Applicant's response to the office action (Paper No.8) is fully considered and is found not persuasive.

5. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 1-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over George Jr. (USPN. 5,451,502) in view of McGavin et al. (J. Mol. Graphics, Vol. 7, pages 218-232, 1989).

George Jr. teaches a catalytic hybridization composition (kit) of claim 1 (see column 4, lines 48-50) and method for assaying binding of claim 24 (see column 3, lines 49-67, column 4, lines 1-35) wherein the method comprises

(a) providing a probe or oligonucleotide containing at least a nucleobase sequence and a scissile linkage (see column 3, lines 49-58);

(b) providing an enzyme adapted to cleave said at least one scissile linkage sequence (see column 3, lines 59-61);

(c) providing a target containing at least one target nucleobase sequence (see column 3, lines 49-61, column 4, lines 19-28);

(d) combining said probe, said enzyme and said target in a hybridization medium (see column 3, lines 62), which contains water, a buffer, and at least one promoter (label) and incubating the reaction mixture to hybridize (see column 13, lines 38-59, column 4, lines 24-28);

(e) cleaving hybridized probes at said at least one scissile linkage to provide unbound probe fragments and detecting said unbound probe fragments to assay binding between said probe and said target (see column 3, lines 63-65, column 4, lines 15-17).

With regard to claims 25-26, George Jr. teaches that the method was carried out at temperatures ranging from 2-60^0 C and pH of the hybridization buffer of about 5 to about 9 (see column 8, lines 34-53, column 10, lines 4-22, column 11, lines 65-68, column 12, lines 1-61);

With regard to claims 27-28, 30-34, George Jr. teaches a flurophore label tethered to a probe with detectable marker using an atom, an inorganic radical (comprise monovalent cation), heavy metal (transition metals) (divalent or valency greater than 1) (see column 6, lines 25-46);

With regard to claim 36, George Jr. teaches that the incubation time is not more than 24 hours (see column 10, lines 23-30, column 12, lines 50-61);

With regard to claims 37-40, George Jr. teaches that the method comprises detecting probe-target hybrid using change in fluorescence, chemiluminescence signal comprising rodhamine and fluorescein (see column 7, lines 1-19);

With regard to claims 41-44, George Jr. teaches that the method comprises energy transfer labels, the signal generated by the labels could be detected as an indication of hybridization of probe with a target (see column 7, lines 8-19);

With reference to claims 53-55, George Jr. teaches said enzyme cleaves only nucleobases having predetermined backbone characteristics (see column 5, lines 29-37);

With regard to claim 56, George Jr. teaches said probe contains at least one interspersed sequence (column 5, lines 41-46);

With regard to claims 62-63, George Jr. teaches said probe comprises an electrical circuit or optically active reporter group adapted to emit a detectable signal (see column 6, lines 25-68).

With regard to claims 2-6, George Jr. teaches at least a portion of the multiplex (target-probe complex) comprises synthetic sequence (probe) or structure (see column 6, lines 20-24), probe and target could be single or double stranded (see column 5, lines 38-68, column 6, lines 1-24); at least a portion of the probe comprises mRNA or cDNA sequences (see column 6, lines 1-24);

With regard to claim 15, 23, George Jr. teaches that the probe comprises 5-57 nucleotides and target contains unlimited number of bases (see column 6, lines 1-24, column 9, lines 11-23);

With regard to claim 16-18, George Jr. teaches that the target could include genomic DNA or PCR product (cDNA) (see column 5, lines 47-68);

With regard to claim 19-22, George Jr. teaches that the multiplex structure (probe-target complex) could be bound to a solid support and solid support is electrically conductive (see column 7, lines 35-49).

However George Jr. did not specifically tech that the multiplex structure (probe-target complex) is bond solely through Watson-Crick base triplets.

With regard to claims 1-63, McGavin et al. teach a multiplex structure using computer graphics wherein McGavin et al. disclose three-strand and four-stranded structure formation solely through Watson-Crick pairing in which Watson-Crick duplexes are paired specifically about a dyad axis coincident with a common long molecular axis and with major grooves in continuous and specific contact (see page 230, column 1, paragraphs 1-3, page 225, column 1, paragraph 2, column 2, paragraph 3, page 230, column 1, paragraphs 1-3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and composition of DNA multiplex complex as taught by George Jr. with the inclusion of Watson-Crick base paring forming model as taught by McGavin et al. in order to obtain the invention as a whole. An ordinary artisan would have motivated to have added the structural stability of Watson-Crick base pairing of nucleic acid strands in a multiplex structure to the method of George Jr., because McGavin et al. taught Watson-Crick kind of base pairing as a strong specific interaction between complementary strands and its growing significance in genetic recombination or specificity of interaction between strands. Therefore an ordinary artisan would have recognized the expected benefits of stability of Watson-Crick kind of base pairing structures and would have motivated to add the limitation to the method and composition of binding assay as taught by George Jr to obtain a more stable multiplex structure.

Response to arguments:

With regard to the above rejection, Applicants' arguments have been fully considered and found not persuasive. Applicants argue that there is no motivation to employ the purely theoretical teachings of McGavin to modify the primary reference, George since the prior art McGavin discloses a theoretical model for quadruplex nucleic acid sequences based on the Watson-Crick tetrads and McGavin is a non-enabling art. These arguments are fully considered and found not persuasive because in previous office action Applicants submitted the same reference to show that the Watson-Crick base pairing is enabled by computer graphic structures disclosed by the McGavin reference. Contradictory to this, presently, Applicants argue that the prior art is non-enabling prior art. Examiner notes that one of ordinary skill in the art would relay on the McGavin reference for the structure as claimed in the instant invention because Applicants did not show any crystallographic data to show how the instantly claimed structure is formed with Watson-Crick base pairing involving more that two strands. It is noted in MPEP 2121.04 "Pictures and drawings may be sufficiently enabling to put the public in the possession of the article pictured. Therefore, such an enabling picture may be used to reject claims to the article. However, the picture must show all the claimed structural features and how they are put together. Jockmus v. Leviton, 28 F.2d 812 (2d Cir. 1928). See also MPEP § 2125 for a discussion of drawings as prior art. Thus the computer graphic structure disclosed by McGavin is considered as enabling art.

Further Applicants' reference to a case law is fully considered However, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is

some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection above, which notes that An ordinary artisan would have motivated to have added the structural stability of Watson-Crick base pairing of nucleic acid strands in a multiplex structure to the method of George Jr., because McGavin et al. taught Watson-Crick kind of base pairing as a strong specific interaction between complementary strands and its growing significance in genetic recombination or specificity of interaction between strands. Therefore an ordinary artisan would have recognized the expected benefits of stability of Watson-Crick kind of base pairing structures and would have motivated to add the limitation to the method and composition of binding assay as taught by George Jr to obtain a more stable multiplex structure. Therefore the rejection is maintained herein.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
February 16, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER